Attorney Docket No. 2426-A-001

Serial No. 09/381,561

United States Court of Appeals for the Federal Circuit

James Jackson, Petitioner or Appellant,

v. **PETITION FOR REVIEW**

Commissioner of Patents and Trademarks, Respondent or Appellee.

James Jackson (name all parties* bringing the petition or appeal) hereby petition/appeal the court for review of the Affirmation of a Final Rejection of U.S. Patent App.. No. 09/381,561 (describe the order or decision and include decision number) of the Board of Patent Appeals & Interferences (name the agency, board, or officer) entered on December 14 2007, _____ (date). The order or decision was received on December 18 2007, _____ (date).

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Date: February 13, 2008

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David A. Jackson

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES RICHARD JACKSON

Appeal 2008-0754
Application 09/381,561
Technology Center 1600

Decided: December 14, 2007

Before DONALD E. ADAMS, ERIC GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an assessment device, which the Examiner has rejected on grounds of obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

"The analysis of tissue or fluid samples is of crucial importance if the appropriate diagnosis of a patient is to be made by a healthcare worker" (Specification 1). The Specification notes that many individuals are in locations that are distant from medical care (*see* Specification 2). According to the Specification, "it may be desirable to analyse the recorded result of an assay by a healthcare worker at a data processing site remote from the patient rather tha[n] rely on the patient to record and report the result of the test" (Specification 2).

Appellant teaches "[i]t is therefore an object of the invention to provide a generic assay and a recording device which efficiently monitors an individual's health status. It is a further object of the invention to provide an assay and recording means wherein said recording means is detachable from said assay means" (Specification 3).

STATEMENT OF THE CASE

The Claims

Claims 20-39 are on appeal. Claims 22-37 have not been argued separately and therefore stand or fall with the representative claims. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claims 20, 21, 38 and 39, which are representative and read as follows:

> 20. An assessment device comprising an assay part adapted to undertake an assay wherein said assay part comprises:
>
> at least one sample application well in fluid connection with at least one primary conduit, wherein either, or both of said application well and said primary conduit, contains material for assaying a fluid sample;
>
> a test ready indicator for determination by a user when a sample has been suitably assayed; and

a recording part which is a detachable from said assay part for the storage of assay information generated by said assay part relating to at least to said sample after said assay has been completed, and wherein said recording part is in data communication with said assay part when attached to said assay part to enable transfer of assay information from said assay part to said recording part for storage;

wherein said recording part only records the said assay information without analyzation there of in a form suitable for onward transmission for subsequent processing an[d] analysis at a remote data processing site.

21. An assessment device according to claim 20 where the detachable recording part is sized to facilitate personal handling by one of said user and a technician, and to facilitate transport of said recording device to a processing facility by a common courier.

38. A method to assay and record a tissue/fluid sample comprising:

i) applying a sample to at least one sample application well of an assay part of an assessment device according to claims 20-37;

ii) mixing said sample with at least one primary assay reagents;

iii) generating assay information relating to said sample; and

iv) recording the assay information via the recording part of the assessment device.

39. A kit comprising an assessment device according to any of claims 20-37 comprising an assessment device, assay reagents and protective packaging for transport of the recording device to a processing facility.

The Examiner has rejected claims 20-39 under 35 U.S.C. § 102(e) based on:

Chow et al. U.S. Patent 5,955,028, September 21, 1999 (hereafter "Chow").

The Issue

The Examiner's position is that Chow discloses "a base unit (12) and adapter (14) to interface an assay substrate (16) with a recording device, such as a computer, to control, record, and/or analyze the data from the assay substrate (col. 5, line 25, to col. 6, line 50)" (Answer 3).

According to the Examiner, "the computer in Chow reads on the recording part of the instant invention since it is detachable, can record assay data, and is in data communication with the assay part through the base unit (12) and adapter (14)" (Answer 5).

Appellant responds that

> the computer (alleged to be analogous to Applicant's recording part) is not a detachable recording part that 'only records the said assay information without analyzation there of in a form suitable for onward transmission for subsequent processing and analysis at a remote data site' as recited by present claim 1.

(App. Br. 7.)

Appellant argues "that the computer (as well as the base unit) disclosed by Chow are stationary, and it is the adapter that is removable from the base unit" (App. Br. 7).

In view of these conflicting positions, we frame the issue before us as follows:

Do either the computer or base unit in the analytical system of Chow fulfill the requirements of a recording part as required by claims 20, 21, 38 and 39?

FINDINGS OF FACT

1. Chow discloses a device that undertakes a variety of specific assays (*see* Chow, col. 3, ll. 1-14).

2. Chow teaches a sample application well in fluid connection with a conduit that contains material for assaying a fluid sample (Chow, figure 2 and col. 11, ll. 48-67).

3. Chow discloses an output signal that indicates when the sample has been assayed (Chow, col. 7, ll. 42-46, col. 12, ll. 1-6).

4. Chow teaches a recording part which comprises a personal computer (Chow, figures 2-3 and col. 12, ll. 54-67).

5. Chow teaches that the "base unit 212, however, will be connected to a general purpose computer 220, e.g. a personal computer or work station, which provides at least a portion of the input/output, control, and computational functions of the system 200" (Chow, col. 12, ll. 61-64).

6. Chow teaches that the "computer 220 may be connected by any conventional connectors, typically using serial or parallel input ports" (Chow, col. 12, ll. 65-66).

7. Chow teaches that the computer will usually be "a standard personal computer" (Chow, col. 5, l. 33).

8. Chow teaches that the computer can store information since it has standard elements such as a "hard disk, floppy disk, CD reader, as well

as user outputs, such as screens, printers, floppy disks, writable CD output, and the like" (Chow, col. 5, ll. 38-40).

9. Chow discloses a method of using the device in which a sample is mixed with the device and reagents, assay information is obtained and the information is transferred to a personal computer (*see* Chow, col. 7, ll. 8-60).

10. Chow teaches that the base unit "will include an attachment region for removably securing the adapter" (Chow, col. 7, ll. 64-65).

11. Chow teaches that the base unit of the device may be "portable or hand-held" (Chow, col. 7, ll. 35-36).

12. Chow teaches that the base unit will "include at least power and/or signal transmission circuits, and will usually include signal processing capability for helping to analyze and/or store data received from the adapter" (Chow, col. 7, ll. 36-39).

13. Chow states that the base unit can "analyze and/or store data" (Chow, col. 7, ll. 38-39). The use of the "and/or" represents a teaching that the base unit can store data without analysis of the data (*see* Chow, col. 7, ll. 38-39).

14. Chow discloses that the computer will not perform any function, including data analysis, without software instructions (*see* Chow, col. 13, ll. 3-20).

Discussion

Claim 20 is drawn to a device with three parts, a sample application well with a conduit which contains assay material, a test ready indicator and a recording part which is in data communication with the assay part but may be detached from the assay part.

There is no dispute that Chow teaches the first two elements of claim 20 (*see* FF 1-3). The arguments center on what claim 20 requires from a "recordable part" and whether the disclosure of Chow teaches elements which satisfy those requirements.

In analyzing the phrase "recordable part" in claim 20, our mandate is to give claims their broadest reasonable interpretation.

> Giving claims their broadest reasonable construction "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified." *Yamamoto*, 740 F.2d at 1571; accord *Hyatt*, 211 F.3d at 1372; *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989) ("An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

In re American Academy of Science Tech Center, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

In analyzing the meaning of the term "recordable part", the Specification notes that in a "preferred embodiment said recording device is a micro processor or other similar electronic device" (Specification 5). The Specification also states the "detection is recorded and stored in a microprocessor located in the recording means, not shown in figure 1" (Specification 12).

A reasonable construction of the "recordable part" of claim 20 is to include any microprocessor device which has the listed functions: (1) the ability to be detached from the assay part, (2) the capacity to store assay information, and (3) the means to be in data communication with the assay part when attached to the assay part.

The microprocessor device must also comply with the wherein clause of claim 20, which states that the "recording part only records the said assay information without analyzation there of in a form suitable for onward transmission for subsequent processing an[d] analysis at a remote data processing site". However, there is no evidence of a structural difference between a microprocessor, which records the information for immediate analysis of information, and a microprocessor, which records the information for later analysis. *See In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997)("[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.") Therefore, the wherein clause is interpreted to include any microprocessor which is inherently capable of recording the information in a form that is accessible for later analysis.

Chow discloses two separate devices that comprise a microprocessor, which can record data from the sample substrate (*see* FF 4-10). The first device taught by Chow is a personal computer (FF 4-7). Chow teaches that the computer meets the first element of a recordable part, since the computer can be connected to the base unit, which inherently requires that the computer can be disconnected (FF 6). Chow also discloses that the computer meets the second and third elements of the recordable part, since the computer can store information (*see* FF 8) and can be in communication with the assay part (*see* FF 6).

The computer of Chow also meets the "wherein clause", since the computer is inherently capable of recording information without analysis (*see* FF 8). As a general purpose computer, the computer of Chow will only analyze the recorded information if specific analysis software is present on the computer and specific instructions are given to implement that software. *See* Chow, col. 13, ll. 2-5 ("The software will comprise instructions for all or a portion of the computer functions. For example, the software may comprise the operating system utilized in performing all assays using the system of the present invention.")

Chow also teaches a second device that meets the requirements of the "recordable part" of claim 20. Chow teaches that the base unit can be detached from the assay portion (FF 10). Chow teaches that the base unit is in data communication with the assay part (FF 12). Chow teaches that the base unit has the capacity to store information noting that the base unit will "usually include signal processing capability for helping to analyze and/or store data received from the adapter" (Chow, col. 7, ll. 36-39). Chow further supports this infomation storage role, noting that the "base unit will usually further include a microprocessor for helping manage both its substrate management and data collection duties" (Chow, col. 7, ll. 40-42).

The base unit of Chow also meets the "wherein" clause of claim 20. When Chow states that the base unit can "analyze and/or store data" the use of the "and/or" represents an express teaching that the base unit can store data without analysis of the data (*see* Chow, col. 7, ll. 38-39).

Therefore, applying the broadest reasonable interpretation to the phrase "recordable part", Chow discloses two different elements which meet

all the limitations of a "recordable part", a personal computer and a base unit (*see* FF 4-12).

Based on the above, we conclude the Examiner has made a prima facie case of anticipation under 35 U.S.C. § 102(e) (FF 1-12).

We reject Appellant's argument that "analysis is not part of the device" (App. Br. 7). First, as already noted, Chow teaches a base unit which functions solely as a data storage device (FF 13). Second, we find that a personal computer is inherently capable of storing information (*see* Chow, col. 11, ll. 7-8). We further find that the computer does not inherently analyze the data unless specific analysis software is present (*see* FF 14). Thus, whether the "recording part" is the base unit or the computer of Chow, in either case, there is no analysis requirement and these units are inherently capable of functioning to store the data without performing any further analysis (FF 13-14).

Appellant argues that "the computer (as well as the base unit) disclosed by Chow are stationary, and it is the adapter that is removable" (App. Br. 7). This argument specifically imputes a limitation regarding whether the recordable part is "stationary" that is not found in the claim. We decline to read this limitation into the claim (*see In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993): "limitations are not to be read into the claims from the specification"). Therefore, we reject Appellant's argument because Chow teaches that the base unit and computer are detachable from the analysis element, the actual requirement found in claim 20 (FF 6, 10).

Appellant argues that claim 21 limits the claim to a detachable recording part which is "sized to facilitate personal handling by one of said

user and a technician, and to facilitate transport of said recording device to a processing facility by a common courier" (App. Br. 8). Appellant has not provided any evidence that either of the base unit of Chow or the personal computer of Chow would not allow personal handling by a user or transport by a common courier. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.") For the base unit, this argument is not correct, since Chow teaches that the base unit of the device may be "portable or hand-held" (Chow, col. 7, ll. 35-36). Also, personal computers are routinely transported by common couriers and the transport of laptop personal computers is omnipresent in airports.

Appellant refers to a "Rule of Subtraction" and argues that based upon this rule, the claims are patentable because they have "fewer features than is taught in the prior art such as Chow" (App. Br. 8). This argument is without merit, since all of the claims utilize the claim phrase "comprising", which is not exclusive and permits the inclusion of additional elements. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). ("'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.")

We also reject Appellant's argument with regard to claim 38 that Chow does not teach application of a sample to a sample application well. Chow expressly states that

> samples may be biological specimens from a patient, but they may also be a wide variety of other biological, chemical, environmental, and other specimens having a component to be characterized or analyte to be detected. The analytical systems may be used to implement numerous

> specific analytical and/or preparative techniques, such as chromatography, PCR, LCR, enzymatic reactions, immunologic reactions, and the like. Samples will usually be liquid or be liquified prior to testing, and will frequently undergo a chemical or biochemical reaction prior to analysis. The analytical systems may provide for a variety of manipulations of the sample in addition to chemical and biological reactions, such as mixing, dispensing, valving, separation, heating, cooling, detection, and the like. . . . In the exemplary and preferred embodiments below, sample manipulation and detection are performed in microfluidic substrates where the sample is manipulated between and among very small volume reservoirs and flow channels formed in the substrate.

(Chow, col. 7, ll. 4-28). When Chow states that the samples may be placed in small volume reservoirs, and discloses in figure 2 that such reservoirs include wells, we conclude that Chow teaches the placement of samples into wells.

We agree with the Examiner that with "respect to protective packaging for the recording device, the computer is Chow is enclosed in a housing. Since the claim does not recite any specific protective packaging, the housing of the computer in Chow reads on the protective packaging" (Answer 7). Further, Chow teaches the assessment device and assay reagents (*see* Chow, col. 12, ll. 7-43). Consequently, we conclude that Chow anticipates the kit claim 39.

CONCLUSION

In summary, we affirm the rejection of claims 20, 21, 38 and 39 under 35 U.S.C. § 102(e). Pursuant to § 41.37(c)(1)(vii)(2006), we also affirm the

rejection of claims 22-37 under 35 U.S.C. § 102(e) as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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